

K051684

MAR 17 2008

510(k) Summary of Safety and Effectiveness

Submitter:

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Rancho Santa Margarita, CA 92688

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Phone: (949) 888-3781

Registration: Pending

Manufacturing Site:
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Official Correspondent: Jacob Liberman, OD, PhD.
Address: 133 KA Drive
Kula, Hawaii
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Device Identification:
Proprietary Name: EYEPOR Vision Training System
Common Name: Vision Training Device
Classification Name: Fixation Device

Side-by-side comparison of the EYEPORT, Gruss Electro Wand and Vis-Flex

	EYE	Gruss Electro Wand	Vis-Flex
Indications for Use	The EYEPORT is indicated for the treatment of poor accommodative and vergence facility, convergence insufficiency and large accommodative lag (in non-presbyopic subjects).	The Gruss Electro Wand was used for the diagnosis and treatment of convergence excess, convergence insufficiency, poor fixations, strabismus, and suppression.	The Vis-Flex is used for training ocular motor skills such as tracking, pursuits, saccadics, fixations, accommodation and convergence.
Target Population	Healthy Individuals	Healthy Individuals	Healthy Individuals
Design	Plastic bar with alternating red and blue lights	Metal bar with lights	Plastic bar with lights
Anatomical Sites	Eyes	Eyes	Eyes
Fundamental Technology	Individual light sources turn on and off to create visual stimuli	Individual light sources turn on and off to create visual stimuli	Individual light sources turn on and off to create visual stimuli
Energy Source	AC adaptor or AA batteries	AC adaptor	AC adaptor
Where Used	In home or optometrist office	In optometrist office	In optometrist office

The only significant differences between the EYEPORT and the two mentioned predicates are overall length of the light bar and color of the light sources. The EYEPORT is 36" long, the Gruss Electro Wand is 27" long and the Vis-Flex is 48" long. The differences in the length are primarily based on practitioner preference.

The EYEPORT makes use of alternating red and blue lights, while the Gruss Electro Wand used and Vis-Flex use only red LED's. The alternating red and blue lights used in the EYEPORT make use of the phenomenon of chromatic aberration to gently rock accommodation and convergence, as the lights are fixated. The red lights used in the Gruss Electro Wand and Vis-Flex function only as fixation targets,



MAY 15 2006

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Exercise Your Eyes™ (EYE), LLC
c/o Jacob Liberman, O.D., Ph.D.
133 KA Drive
Kula, HI 96790

Re: K051684
Trade Name: EYEPORIT™ Visual Training System
Regulation Number: 21 CFR 886.1290
Regulation Name: Fixation Device
Regulatory Class: Class I
Product Code: NXR
Dated: March 6, 2006
Received: March 7, 2006

Dear Dr. Liberman:

This letter corrects our substantially equivalent letter of March 17, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "MB Eydelman, MD", with a stylized flourish at the end.

Malvina B. Eydelman, M.D.

Division Director

Division of Ophthalmic and Ear,

Nose and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051684

Device Name: EYEPOR Vision Training System

Indications For Use: The EYEPOR is indicated for the treatment of poor accommodative and vergence facility, convergence insufficiency and large accommodative lag (in non-presbyopic subjects).

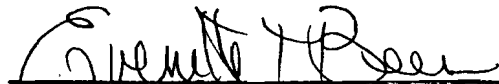
Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices

510(k) Number K051684

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